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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,832	01/14/2004	Herbert W. Virgin	60005161-0168	5585

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,832	VIRGIN, HERBERT W.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 and 36-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12-14 and 36-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>attached</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

1. During a phone interview with Saul Zackman, the examiner was informed that a preliminary amendment had been filed on August 3, 2005. The restriction requirement that was mailed on August 11, 2005 is no longer applicable to the newly added/amended claims of the August 3, 2005 amendment. Therefore, the previous restriction is vacated, and a new restriction is presented below.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 12-14, 46-48, 57 and 59 are drawn to a polypeptide of SEQ ID NO: 2, 3, or 4, classified in class 530, subclass 300.
 - ❖ Further restriction is required from Group I. Applicant must elect one sequence of SEQ ID NO: 2-4, for search and examination.
 - II. Claims 36-45, drawn to a method of detecting antibodies against MNV-1, classified in class 424, subclass 130.1.
 - III. Claims 49, 50 and 54-56, drawn to a method of making an assay surface comprising polypeptides, classified in class 435, subclass 5.
 - IV. Claims 51-53, drawn to a method of making an assay surface comprising cells that express polypeptides, classified in class 435, subclass 4.
 - V. Claim 58, drawn to a reagent that detects binding of antibody with polypeptide, classified in class 435, subclass 6.

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VI. Claims 60-62, drawn to a method of detecting MNV-1, classified in class 435, subclass 5.

❖ Further restriction is required from claim 62. Applicant is required to elect one pair of primers. For example, SEQ ID NO: 15 and SEQ ID NO: 16.

3. The inventions are distinct, each from the other because of the following reasons:

a) Restriction between polypeptides of SEQ ID NO: 2-4, and primers SEQ ID NO: 15-20, respectively, is required because each sequence is different in terms of amino acids, nucleotides, number of residues and bases, and the encoded proteins. No product from these sequences will result in the exact same product. Further, a search for each sequence requires searching against every amino acid and nucleic acid sequence in all of the PTO sequence databases. Such a search would be a serious burden on the Office.

b) The polypeptides of Group I and the methods of Groups II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The polypeptide can be used in a materially different method of use, such as inducing an immune response in a test animal, or for epitope mapping.

c) The polypeptide of Group I and the reagent of Group V are distinct products. It is unclear what Group V is, however, if it is an antibody, then the antibody and the polypeptides of Group I are structurally different. A search for a polypeptide will not necessarily reveal literature that speaks to the antibodies that bind the complex of antibody/polypeptide.

d) The polypeptide of Group I and the method of Group VI are unrelated because the polypeptide is not disclosed as capable of use in the method of Group VI.

e) Groups II-IV are drawn to distinct methods making use of polypeptides and antibodies. These methods require different method steps for detecting antibodies, making surfaces with polypeptides and making surfaces with cells that express the polypeptides. The outcomes of the methods are not the same, nor would the steps be the same since detecting and producing surfaces with polypeptides do not share common method steps with each other.

f) Groups II and V may be related as product and process of using. (The actual product of Group V is unknown.) If the detecting method of Group II uses the product of Group V, then the product of Group can be used in a materially different method, such as inducing an immune response in a test animal or epitope mapping.

g) Groups (II-V) and VI are not related because the method of Group VI does not use the methods or product of Groups II-V.

h) Groups III and V may be related as product and process of using. (The actual product of Group V is unknown.) If the detecting method of Group III uses the product of Group V, then the product of Group can be used in a materially different method, such as inducing an immune response in a test animal or epitope mapping.

i) Groups IV and V are unrelated because the method of Group IV does not require a reagent of Group V.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each Group is not required for the other Groups because each Group requires a different non-

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patent literature search due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above


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policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Stacy B. Chen
August 19, 2005